

TITLE	107: Use and Disclosure of Personal Information
SCOPE	The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator, and TWU researchers
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 PURPOSE

This standard operating procedure (SOP) describes the duties of the Human Research Ethics Board (HREB) and the HREB office in the protection of the Personal Information (PI) of research participants.

2.0 RESPONSIBILITIES

The Researcher is responsible for submitting information to the HREB and to the participant regarding the nature of the PI (including personal health information (PHI)) that will be collected for the research, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of and protected.

The HREB Chair, HREB members and the HREB Office Personnel are responsible for maintaining the confidentiality of any PI received by the HREB office during the course of the research.

Each organization's privacy office is responsible for providing Researchers and research staff with guidance on privacy policies and regulations.

3.0 DEFINITIONS

See Glossary of Terms.

4.0 PROCEDURE

Privacy is a fundamental value that is essential for the protection and promotion of human dignity. Breaches in privacy and confidentiality may cause harm to individuals or groups of individuals. Hence, PI must be collected, used and disclosed in a manner that respects a research participant's right to privacy, and in accordance with applicable federal and provincial privacy regulations.

Privacy regulations permit the use and the limited disclosure of PI for research purposes as long as certain requirements are met. One of the key ethical challenges for the health research community is in protecting appropriately the privacy and confidentiality of PI used for research purposes. The HREB plays an important role in balancing the need for research against the risk of the infringement of privacy and in minimizing invasions of privacy for research participants. Individuals should be protected from any harm that may be caused by the unauthorized use of their PI and they should expect that their rights to privacy and confidentiality are respected.

4.1 HREB Review of Privacy Concerns

- 4.1.1 The HREB shall review the research submitted to determine if the Researcher has access to and/or is using PI and whether appropriate privacy legislation is adhered to;
- 4.1.2 In reviewing the research, the HREB will include such privacy considerations as:
 - The type of PI to be collected,
 - The research objectives and justification for the requested personal data needed to fulfill these objectives,
 - The purpose for which the personal data will be used,
 - How the personal data will be controlled, accessed, disclosed, and de-identified,
 - Limits on the use, disclosure and retention of the personal data,
 - Any anticipated secondary uses of identifiable data from the research,
 - Any anticipated linkage of personal data gathered in the research with other data about research participants, whether those data are contained in public or in personal records,
 - Whether consent for access to, or the collection of personal data from participants is required,
 - How consent is managed and documented,
 - If and how prospective research participants will be informed of the research,
 - How prospective research participants will be recruited,
 - The administrative, technical and physical safeguards and practices in place to protect the personal data including de-identification strategies and managed linkages to identifiable data,
 - How accountability and transparency in the management of personal data will be ensured;
- 4.1.3 The HREB must find that there are adequate provisions to protect the privacy interests of participants before approving the research.

- 4.1.4 In situations where there is an attempt to compel disclosure of confidential participant information by legal means, TWU will provide researchers with financial and other support to obtain the independent legal advice which permits the researcher to make an informed decision as to whether disclosure or resistance is warranted.
- If resistance is warranted, institutional support includes the independent legal advice which makes that resistance possible, or ensuring that such support is provided. It is recognized, however, that the personnel and financial resources of the institution are limited. Support levels for cases calling for resistance will be determined by consultation among the researcher, university administration and the HREB.
 - In cases where independent legal counsel determines that resistance is not warranted, the university will not provide support to pursue resistance.

4.2 Receipt, Use and Disclosure of PI

- 4.2.1 The HREB Chair, HREB members and the HREB Office Personnel are bound by confidentiality agreements signed prior to commencement of their duties;
- 4.2.2 The HREB does not intentionally collect PI;
- 4.2.3 Subject to consent, as applicable, the HREB is permitted to access PI for the purposes of the review, the approval, the ongoing monitoring, and/or the auditing of the conduct of the research;
- 4.2.4 The HREB office must adopt reasonable safeguards and ensure that there is training for HREB Office Personnel to protect PI from unauthorized access;
- 4.2.5 HREB members or HREB Office Personnel may consult with the HREB Chair or designee if they are uncertain about the appropriate use or disclosure of PI;
- 4.2.6 If any PI is received inadvertently in the HREB office (e.g. disclosed by a Researcher), appropriate notification must take place and any corrective action that is required including, if applicable, notification to the appropriate Organizational Official. The facts surrounding the breach, the appropriate steps taken to manage the breach, remedial activities to address the breach and the outcome will be documented. The PI will be destroyed in a secure manner as per the organizational policies and procedures;
- 4.2.7 If there is an internal breach involving the use or dissemination of PI, the HREB Chair or designee will be notified, and if applicable, notification of the appropriate Organizational Official, and a determination will be made in a timely manner regarding a corrective action plan. This process may

include notification, containment, investigation and remediation, and strategies for prevention. The facts surrounding the breach, the appropriate steps taken to manage the breach and the outcome will be documented. The PI will be destroyed in a secure manner as per the organizational policies and procedures;

- 4.2.8 At the discretion of the HREB Chair or designee, in consultation with the organization, the provincial privacy office (or equivalent) may be notified.

5.0 REFERENCES

See References.

6.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 107	November 14, 2019	Original version